K000386

510(k) Notification
43S11 Polygram 98 Anorectal Function Testing Application

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 SKOVLUNDE
Tel: + 45 44 57 95 02
Fax: + 45 44 57 90 10
Contact person for this submission: Tove Kjaer
Date submission was prepared: January 28, 2000

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Polygram 98 Anorectal Function Testing Application

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Polygram 98 Anorectal Function Testing Application	78 FFX	II	21 CFR 876.1725

3. Predicate Device Identification:

The scientific technology and the functionality and intended use of the Polygram 98Anorectal Function Testing Application for the Polygraf ID is equivalent to Medtronic Synectics Anorectal Manomentry Analysis Module (K972439).

4. Device Description:

The Polygram 98 Anorectal Function Testing Application is together with Polygraf ID used to assess the function of the anorectal canal. Data is collected in the anorectal canal, using sensors and a recording device (Polygraf ID) and then analyzed. The parameters are presented during the capture and are also recorded for later display, analysis and reporting. The results are used to help diagnose pelvic floor function disorders.

In its daily use, a trained tecnician and/or a physician are the main user of the system.

The main tasks when performing a manometry procedure with a stationary manometry system are:

- Prepare equipment including calibration
- Enter patient/study demographic information
- Perform procedure and obtain relevant data
- Review, analysis and post procedure activities
- Create and print a report

The Polygram 98 Anorectal Function Testing Application software runs on Microsoft Windows® 98.

5. Intended Use:

The Polygraf ID with Polygram 98 Anorectal Function Testing Application software is intended to record, store, view and analyze data on line in the gastrointestinal tract including rectum and pelvic floor* to assist in diagnosing disorders in these areas.

*Expanded indication for use due to the Polygram 98 Anorectal Function Testing Application.

6. Table of Device Similarities and differences to predicate device

Manufacturer	Medtronic Synectics AB	Medtronic Functional Diagnostics	–
510(k) number	***Predicate Device*** • Anorectal Manometry Analysis Module for Polygraf HR – K 972439	***Modified Device*** • Polygram 98 Anorectal Function Testing Application **K number to be decided**	–

General:	***Predicate devics:***	***Modified Device***	***Explanation of the differences compared to the Predicate device***
Intended Use / Indication of Use	Analyse pressure data recorded from the lower gastrointestinal tract.	Same	---
Intended Populations	Pediatric to Adults	Same	---
Sterilization	Accessories are not supplied sterile, manufacturer label the accessories with cleaning instructions.	Same	---
Biocompatibility	Sensors are the only part that comes into contact with the patients.	Same	---

Features:	***Predicate devices***	***Modified Device***	***Explanation of the differences compared to the Predicate device***
Signal to measure	Pressure, EMG	Same	
Analyzing signals	Pressure data is analyzed in terms of physiological properties, comparison with normal values, etc.	Same	---
Data displayed	Raw signal data	Same	
User commands	Menu selections	Same	---
Software Environment	Dos and Windows	Windows	Windows 98
Reports	Signal tracings and reports.	Same	---
Patient database	Database	Same	---
Additional patient data	Comment field	Same	---
User help system	Separate command description	Same	---
Signal review method	Time – tracing based	Same	---
Recording control	Real time monitoring of signals	Same	---
Recording configur.	User definable configuration	Same	---

7. Assessment of non-clinical performance data for equivalence:

Verifications results shows that the enhanced system performs as its predicate system.

8. Assessment of clinical performance data for equivalence:

Clinical trials are not performed. This new system does not raise any new safety or performance issues.

9. Biocompatability:

Not applicable

10. Sterilization:

Not applicable

11. Standards and Guidances:

The Stationary Manometry System Polygraf ID conforms to the following voluntary and mandatory standards:

- EN 60601-1, Medical equipment
- EN 60601-1-1, Electrical Safety
- EN 60601-1-2, Electro magnetic Compatibility
- CAN/CSA 22.2 No. 601.1 – M90

The Polygram 98 Anorectal Function Testing Application is a pure software enabling and does not affect the hardware.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2000

Ms. Tove Kjaer
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
DENMARK

Re: K000386
Trade Name: Polygraf ID/Polygram 98 Anorectal Function Testing Software
Regulatory Class: II
Product Code: 78 FFX/21CFR §876.1725
Dated: February 2, 2000
Received: February 7, 2000

Dear Ms. Kjaer:

This letter corrects our substantially equivalent letter of May 5, 2000, regarding the indications for use and 510(k) Summary.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the new indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

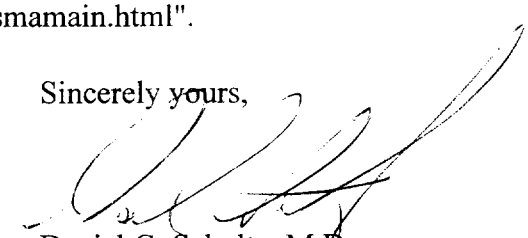
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and

Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indication for Use Statement

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510(k) Number (if known): K000386

Device Name: **Polygram 98 Anorectal Function Testing Application**

Indications for Use:

The Polygraf ID with Polygram 98 Anorectal Function Testing Application software is intended to record, store, view and analyze data on line in the gastrointestinal tract including rectum and pelvic floor* to assist in diagnosing disorders in these areas.

*Expanded indication for use due to the Anorectal Function Testing Application.

MRI Compatibility Statement:

The Polygraf ID with Polygram 98 Anorectal Function Testing Application is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000386

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)